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K090419
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5. 510(K) SUMMARY:

510(k) Summary of Safety and Effectiveness:

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473
CONTACT PERSON:	Robert Zott Program Director, Regulatory Affairs Phone: (203) 492-6013 Fax: (203) 492-5029
DATE PREPARED:	February 17, 2009
TRADE/PROPRIETARY NAME:	SILS™ Stitch
COMMON/USUAL NAME:	Endoscopic Suturing Device
CLASSIFICATION NAME:	Endoscope and accessories
PREDICATE DEVICE(S):	K082659: Modified Endo Stitch™ Endoscopic Suturing Device The predicate device is manufactured by Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)
PRIOR RELATED SUBMISSION(S):	K072814: Convenience Kit for "Single-Incision Laparoscopic Surgery and other advanced laparoscopic procedures." K082619: SILS™ Port for Multiple Instrument Laparoscopic Access Through a Single Incision.
DEVICE DESCRIPTION:	SILS™ Stitch is an endoscopic suturing device that contains two jaws at its distal end, with opposing handles and a toggle lever at its proximal end.

INTENDED USE:	For use in endoscopic surgery for the placement of interrupted or running stitches in soft tissues
TECHNOLOGICAL CHARACTERISTICS:	The device holds and passes a needled suture between the two jaws. The suture needle is passed from one jaw to another by squeezing the opposing handles and secured in each jaw by activating the toggle lever.
MATERIALS:	All patient contact materials in the SILS™ Stitch have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices -- Part 1: Evaluation and Testing.
PERFORMANCE DATA:	No additional in-vitro or in-vivo testing has been performed in support of the intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Covidien
% Mr. Robert Zott
Program Director, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K090419
Trade/Device Name: SILS™ Stitch – Endoscopic Suturing Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: February 17, 2009
Received: February 18, 2009

Dear Mr. Zott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090419

Device Name: SILS™ Stitch - Endoscopic Suturing Device

Indications For Use: The SILS™ Stitch 10 mm single use suturing device has application in endoscopic surgery for the placement of interrupted or running stitches in soft tissues

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for NKM 3/9/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090419